

1 amendments made by this title to such provision of law
2 for such fiscal year.

3 **Subtitle F—Over-the-Counter**
4 **Drugs**

5 **PART I—OTC DRUG REVIEW**

6 **SEC. 3851. REGULATION OF CERTAIN NONPRESCRIPTION**
7 **DRUGS THAT ARE MARKETED WITHOUT AN**
8 **APPROVED DRUG APPLICATION.**

9 (a) IN GENERAL.—Chapter V of the Federal Food,
10 Drug, and Cosmetic Act is amended by inserting after sec-
11 tion 505F of such Act (21 U.S.C. 355g) the following:

12 **“SEC. 505G. REGULATION OF CERTAIN NONPRESCRIPTION**
13 **DRUGS THAT ARE MARKETED WITHOUT AN**
14 **APPROVED DRUG APPLICATION.**

15 “(a) NONPRESCRIPTION DRUGS MARKETED WITH-
16 OUT AN APPROVED APPLICATION.—Nonprescription
17 drugs marketed without an approved drug application
18 under section 505, as of the date of the enactment of this
19 section, shall be treated in accordance with this sub-
20 section.

21 “(1) DRUGS SUBJECT TO A FINAL MONOGRAPH;
22 CATEGORY I DRUGS SUBJECT TO A TENTATIVE
23 FINAL MONOGRAPH.—A drug is deemed to be gen-
24 erally recognized as safe and effective under section

1 under part 330 of title 21, Code of Federal
2 Regulations;

3 “(ii) in conformity with the proposed
4 requirements for nonprescription use of
5 such tentative final monograph, any appli-
6 cable subsequent determination by the Sec-
7 retary, the general requirements for non-
8 prescription drugs, and conditions or re-
9 quirements under subsections (b), (c), and
10 (k); and

11 “(iii) except as permitted by an order
12 issued under subsection (b) or, in the case
13 of a minor change in the drug, in con-
14 formity with an order issued under sub-
15 section (c), in a dosage form that, imme-
16 diately prior to the date of the enactment
17 of this section, has been used to a material
18 extent and for a material time under sec-
19 tion 201(p)(2).

20 “(2) TREATMENT OF SUNSCREEN DRUGS.—

21 With respect to sunscreen drugs subject to this sec-
22 tion, the applicable requirements in terms of con-
23 formity with a final monograph, for purposes of
24 paragraph (1)(A)(i), shall be the requirements speci-
25 fied in part 352 of title 21, Code of Federal Regula-

1 tions, as published on May 21, 1999, beginning on
2 page 27687 of volume 64 of the Federal Register,
3 except that the applicable requirements governing ef-
4 fectiveness and labeling shall be those specified in
5 section 201.327 of title 21, Code of Federal Regula-
6 tions.

7 “(3) CATEGORY III DRUGS SUBJECT TO A TEN-
8 TATIVE FINAL MONOGRAPH; CATEGORY I DRUGS
9 SUBJECT TO PROPOSED MONOGRAPH OR ADVANCE
10 NOTICE OF PROPOSED RULEMAKING.—A drug that
11 is not described in paragraph (1), (2), or (4) is not
12 required to be the subject of an application approved
13 under section 505, and is not subject to section
14 503(b)(1), if—

15 “(A) the drug is—

16 “(i) classified in category III for safe-
17 ty or effectiveness in the preamble of a
18 proposed rule establishing a tentative final
19 monograph that is the most recently appli-
20 cable proposal or determination for such
21 drug issued under part 330 of title 21,
22 Code of Federal Regulations;

23 “(ii) in conformity with—

24 “(I) the conditions of use, includ-
25 ing indication and dosage strength, if

1 any, described for such category III
2 drug in such preamble or in an appli-
3 cable subsequent proposed rule;

4 “(II) the proposed requirements
5 for drugs classified in such tentative
6 final monograph in category I in the
7 most recently proposed rule estab-
8 lishing requirements related to such
9 tentative final monograph and in any
10 final rule establishing requirements
11 that are applicable to the drug; and

12 “(III) the general requirements
13 for nonprescription drugs and condi-
14 tions or requirements under sub-
15 section (b) or (k); and

16 “(iii) in a dosage form that, imme-
17 diately prior to the date of the enactment
18 of this section, had been used to a material
19 extent and for a material time under sec-
20 tion 201(p)(2); or

21 “(B) the drug is—

22 “(i) classified in category I for safety
23 and effectiveness under a proposed mono-
24 graph or advance notice of proposed rule-
25 making that is the most recently applicable

1 proposal or determination for such drug
2 issued under part 330 of title 21, Code of
3 Federal Regulations;

4 “(ii) in conformity with the require-
5 ments for nonprescription use of such pro-
6 posed monograph or advance notice of pro-
7 posed rulemaking, any applicable subse-
8 quent determination by the Secretary, the
9 general requirements for nonprescription
10 drugs, and conditions or requirements
11 under subsection (b) or (k); and

12 “(iii) in a dosage form that, imme-
13 diately prior to the date of the enactment
14 of this section, has been used to a material
15 extent and for a material time under sec-
16 tion 201(p)(2).

17 “(4) CATEGORY II DRUGS DEEMED NEW
18 DRUGS.—A drug that is classified in category II for
19 safety or effectiveness under a tentative final mono-
20 graph or that is subject to a determination to be not
21 generally recognized as safe and effective in a pro-
22 posed rule that is the most recently applicable pro-
23 posal issued under part 330 of title 21, Code of Fed-
24 eral Regulations, shall be deemed to be a new drug
25 under section 201(p), misbranded under section

1 502(ee), and subject to the requirement for an ap-
2 proved new drug application under section 505 be-
3 ginning on the day that is 180 calendar days after
4 the date of the enactment of this section, unless, be-
5 fore such day, the Secretary determines that it is in
6 the interest of public health to extend the period
7 during which the drug may be marketed without
8 such an approved new drug application.

9 “(5) DRUGS NOT GRASE DEEMED NEW
10 DRUGS.—A drug that the Secretary has determined
11 not to be generally recognized as safe and effective
12 under section 201(p)(1) under a final determination
13 issued under part 330 of title 21, Code of Federal
14 Regulations, shall be deemed to be a new drug under
15 section 201(p), misbranded under section 502(ee),
16 and subject to the requirement for an approved new
17 drug application under section 505.

18 “(6) OTHER DRUGS DEEMED NEW DRUGS.—
19 Except as provided in subsection (m), a drug is
20 deemed to be a new drug under section 201(p) and
21 misbranded under section 502(ee) if the drug—

22 “(A) is not subject to section 503(b)(1);

23 and

24 “(B) is not described in paragraph (1),

25 (2), (3), (4), or (5), or subsection (b)(1)(B).

1 “(b) ADMINISTRATIVE ORDERS.—

2 “(1) IN GENERAL.—

3 “(A) DETERMINATION.—The Secretary
4 may, on the initiative of the Secretary or at the
5 request of one or more requestors, issue an ad-
6 ministrative order determining whether there
7 are conditions under which a specific drug, a
8 class of drugs, or a combination of drugs, is de-
9 termined to be—

10 “(i) not subject to section 503(b)(1);

11 and

12 “(ii) generally recognized as safe and
13 effective under section 201(p)(1).

14 “(B) EFFECT.—A drug or combination of
15 drugs shall be deemed to not require approval
16 under section 505 if such drug or combination
17 of drugs—

18 “(i) is determined by the Secretary to
19 meet the conditions specified in clauses (i)
20 and (ii) of subparagraph (A);

21 “(ii) is marketed in conformity with
22 an administrative order under this sub-
23 section;

24 “(iii) meets the general requirements
25 for nonprescription drugs; and

1 “(iv) meets the requirements under
2 subsections (e) and (k).

3 “(C) STANDARD.—The Secretary shall find
4 that a drug is not generally recognized as safe
5 and effective under section 201(p)(1) if—

6 “(i) the evidence shows that the drug
7 is not generally recognized as safe and ef-
8 fective under section 201(p)(1); or

9 “(ii) the evidence is inadequate to
10 show that the drug is generally recognized
11 as safe and effective under section
12 201(p)(1).

13 “(2) ADMINISTRATIVE ORDERS INITIATED BY
14 THE SECRETARY.—

15 “(A) IN GENERAL.—In issuing an adminis-
16 trative order under paragraph (1) upon the
17 Secretary’s initiative, the Secretary shall—

18 “(i) make reasonable efforts to notify
19 informally, not later than 2 business days
20 before the issuance of the proposed order,
21 the sponsors of drugs who have a listing in
22 effect under section 510(j) for the drugs or
23 combination of drugs that will be subject
24 to the administrative order;

1 “(ii) after any such reasonable efforts
2 of notification—

3 “(I) issue a proposed administra-
4 tive order by publishing it on the
5 website of the Food and Drug Admin-
6 istration and include in such order the
7 reasons for the issuance of such order;
8 and

9 “(II) publish a notice of avail-
10 ability of such proposed order in the
11 Federal Register;

12 “(iii) except as provided in subpara-
13 graph (B), provide for a public comment
14 period with respect to such proposed order
15 of not less than 45 calendar days; and

16 “(iv) if, after completion of the pro-
17 ceedings specified in clauses (i) through
18 (iii), the Secretary determines that it is ap-
19 propriate to issue a final administrative
20 order—

21 “(I) issue the final administrative
22 order, together with a detailed state-
23 ment of reasons, which order shall not
24 take effect until the time for request-

1 ing judicial review under paragraph
2 (3)(D)(ii) has expired;

3 “(II) publish a notice of such
4 final administrative order in the Fed-
5 eral Register;

6 “(III) afford requestors of drugs
7 that will be subject to such order the
8 opportunity for formal dispute resolu-
9 tion up to the level of the Director of
10 the Center for Drug Evaluation and
11 Research, which initially must be re-
12 quested within 45 calendar days of
13 the issuance of the order, and, for
14 subsequent levels of appeal, within 30
15 calendar days of the prior decision;
16 and

17 “(IV) except with respect to
18 drugs described in paragraph (3)(B),
19 upon completion of the formal dispute
20 resolution procedure, inform the per-
21 sons which sought such dispute reso-
22 lution of their right to request a hear-
23 ing.

24 “(B) EXCEPTIONS.—When issuing an ad-
25 ministrative order under paragraph (1) on the

1 Secretary's initiative proposing to determine
2 that a drug described in subsection (a)(3) is not
3 generally recognized as safe and effective under
4 section 201(p)(1), the Secretary shall follow the
5 procedures in subparagraph (A), except that—

6 “(i) the proposed order shall include
7 notice of—

8 “(I) the general categories of
9 data the Secretary has determined
10 necessary to establish that the drug is
11 generally recognized as safe and effec-
12 tive under section 201(p)(1); and

13 “(II) the format for submissions
14 by interested persons;

15 “(ii) the Secretary shall provide for a
16 public comment period of no less than 180
17 calendar days with respect to such pro-
18 posed order, except when the Secretary de-
19 termines, for good cause, that a shorter pe-
20 riod is in the interest of public health; and

21 “(iii) any person who submits data in
22 such comment period shall include a cer-
23 tification that the person has submitted all
24 evidence created, obtained, or received by
25 that person that is both within the cat-

1 egories of data identified in the proposed
2 order and relevant to a determination as to
3 whether the drug is generally recognized as
4 safe and effective under section 201(p)(1).

5 “(3) HEARINGS; JUDICIAL REVIEW.—

6 “(A) IN GENERAL.—Only a person who
7 participated in each stage of formal dispute res-
8 olution under subclause (III) of paragraph
9 (2)(A)(iv) of an administrative order with re-
10 spect to a drug may request a hearing con-
11 cerning a final administrative order issued
12 under such paragraph with respect to such
13 drug. If a hearing is sought, such person must
14 submit a request for a hearing, which shall be
15 based solely on information in the administra-
16 tive record, to the Secretary not later than 30
17 calendar days after receiving notice of the final
18 decision of the formal dispute resolution proce-
19 dure.

20 “(B) NO HEARING REQUIRED WITH RE-
21 SPECT TO ORDERS RELATING TO CERTAIN
22 DRUGS.—

23 “(i) IN GENERAL.—The Secretary
24 shall not be required to provide notice and
25 an opportunity for a hearing pursuant to

1 paragraph (2)(A)(iv) if the final adminis-
2 trative order involved relates to a drug—

3 “(I) that is described in sub-
4 section (a)(3)(A); and

5 “(II) with respect to which no
6 human or non-human data studies rel-
7 evant to the safety or effectiveness of
8 such drug have been submitted to the
9 administrative record since the
10 issuance of the most recent tentative
11 final monograph relating to such
12 drug.

13 “(ii) HUMAN DATA STUDIES AND
14 NON-HUMAN DATA DEFINED.—In this sub-
15 paragraph:

16 “(I) The term ‘human data stud-
17 ies’ means clinical trials of safety or
18 effectiveness (including actual use
19 studies), pharmacokinetics studies, or
20 bioavailability studies.

21 “(II) The term ‘non-human data’
22 means data from testing other than
23 with human subjects which provides
24 information concerning safety or ef-
25 fectiveness.

1 “(C) HEARING PROCEDURES.—

2 “(i) DENIAL OF REQUEST FOR HEAR-
3 ING.—If the Secretary determines that in-
4 formation submitted in a request for a
5 hearing under subparagraph (A) with re-
6 spect to a final administrative order issued
7 under paragraph (2)(A)(iv) does not iden-
8 tify the existence of a genuine and sub-
9 stantial question of material fact, the Sec-
10 retary may deny such request. In making
11 such a determination, the Secretary may
12 consider only information and data that
13 are based on relevant and reliable scientific
14 principles and methodologies.

15 “(ii) SINGLE HEARING FOR MULTIPLE
16 RELATED REQUESTS.—If more than one
17 request for a hearing is submitted with re-
18 spect to the same administrative order
19 under subparagraph (A), the Secretary
20 may direct that a single hearing be con-
21 ducted in which all persons whose hearing
22 requests were granted may participate.

23 “(iii) PRESIDING OFFICER.—The pre-
24 siding officer of a hearing requested under
25 subparagraph (A) shall—

1 “(I) be designated by the Sec-
2 retary;

3 “(II) not be an employee of the
4 Center for Drug Evaluation and Re-
5 search; and

6 “(III) not have been previously
7 involved in the development of the ad-
8 ministrative order involved or pro-
9 ceedings relating to that administra-
10 tive order.

11 “(iv) RIGHTS OF PARTIES TO HEAR-
12 ING.—The parties to a hearing requested
13 under subparagraph (A) shall have the
14 right to present testimony, including testi-
15 mony of expert witnesses, and to cross-ex-
16 amine witnesses presented by other parties.
17 Where appropriate, the presiding officer
18 may require that cross-examination by par-
19 ties representing substantially the same in-
20 terests be consolidated to promote effi-
21 ciency and avoid duplication.

22 “(v) FINAL DECISION.—

23 “(I) At the conclusion of a hear-
24 ing requested under subparagraph
25 (A), the presiding officer of the hear-

1 ing shall issue a decision containing
2 findings of fact and conclusions of
3 law. The decision of the presiding offi-
4 cer shall be final.

5 “(II) The final decision may not
6 take effect until the period under sub-
7 paragraph (D)(ii) for submitting a re-
8 quest for judicial review of such deci-
9 sion expires.

10 “(D) JUDICIAL REVIEW OF FINAL ADMIN-
11 ISTRATIVE ORDER.—

12 “(i) IN GENERAL.—The procedures
13 described in section 505(h) shall apply
14 with respect to judicial review of final ad-
15 ministrative orders issued under this sub-
16 section in the same manner and to the
17 same extent as such section applies to an
18 order described in such section except that
19 the judicial review shall be taken by filing
20 in an appropriate district court of the
21 United States in lieu of the appellate
22 courts specified in such section.

23 “(ii) PERIOD TO SUBMIT A REQUEST
24 FOR JUDICIAL REVIEW.—A person eligible
25 to request a hearing under this paragraph

1 and seeking judicial review of a final ad-
2 ministrative order issued under this sub-
3 section shall file such request for judicial
4 review not later than 60 calendar days
5 after the latest of—

6 “(I) the date on which notice of
7 such order is published;

8 “(II) the date on which a hearing
9 with respect to such order is denied
10 under subparagraph (B) or (C)(i);

11 “(III) the date on which a final
12 decision is made following a hearing
13 under subparagraph (C)(v); or

14 “(IV) if no hearing is requested,
15 the date on which the time for re-
16 questing a hearing expires.

17 “(4) EXPEDITED PROCEDURE WITH RESPECT
18 TO ADMINISTRATIVE ORDERS INITIATED BY THE
19 SECRETARY.—

20 “(A) IMMINENT HAZARD TO THE PUBLIC
21 HEALTH.—

22 “(i) IN GENERAL.—In the case of a
23 determination by the Secretary that a
24 drug, class of drugs, or combination of
25 drugs subject to this section poses an im-

1 minent hazard to the public health, the
2 Secretary, after first making reasonable ef-
3 forts to notify, not later than 48 hours be-
4 fore issuance of such order under this sub-
5 paragraph, sponsors who have a listing in
6 effect under section 510(j) for such drug
7 or combination of drugs—

8 “(I) may issue an interim final
9 administrative order for such drug,
10 class of drugs, or combination of
11 drugs under paragraph (1), together
12 with a detailed statement of the rea-
13 sons for such order;

14 “(II) shall publish in the Federal
15 Register a notice of availability of any
16 such order; and

17 “(III) shall provide for a public
18 comment period of at least 45 cal-
19 endar days with respect to such in-
20 terim final order.

21 “(ii) NONDELEGATION.—The Sec-
22 retary may not delegate the authority to
23 issue an interim final administrative order
24 under this subparagraph.

25 “(B) SAFETY LABELING CHANGES.—

1 “(i) IN GENERAL.—In the case of a
2 determination by the Secretary that a
3 change in the labeling of a drug, class of
4 drugs, or combination of drugs subject to
5 this section is reasonably expected to miti-
6 gate a significant or unreasonable risk of
7 a serious adverse event associated with use
8 of the drug, the Secretary may—

9 “(I) make reasonable efforts to
10 notify informally, not later than 48
11 hours before the issuance of the in-
12 terim final order, the sponsors of
13 drugs who have a listing in effect
14 under section 510(j) for such drug or
15 combination of drugs;

16 “(II) after reasonable efforts of
17 notification, issue an interim final ad-
18 ministrative order in accordance with
19 paragraph (1) to require such change,
20 together with a detailed statement of
21 the reasons for such order;

22 “(III) publish in the Federal
23 Register a notice of availability of
24 such order; and

1 “(IV) provide for a public com-
2 ment period of at least 45 calendar
3 days with respect to such interim final
4 order.

5 “(ii) CONTENT OF ORDER.—An in-
6 terim final order issued under this sub-
7 paragraph with respect to the labeling of a
8 drug may provide for new warnings and
9 other information required for safe use of
10 the drug.

11 “(C) EFFECTIVE DATE.—An order under
12 subparagraph (A) or (B) shall take effect on a
13 date specified by the Secretary.

14 “(D) FINAL ORDER.—After the completion
15 of the proceedings in subparagraph (A) or (B),
16 the Secretary shall—

17 “(i) issue a final order in accordance
18 with paragraph (1);

19 “(ii) publish a notice of availability of
20 such final administrative order in the Fed-
21 eral Register; and

22 “(iii) afford sponsors of such drugs
23 that will be subject to such an order the
24 opportunity for formal dispute resolution
25 up to the level of the Director of the Cen-

1 or (B), issue a final order in accord-
2 ance with paragraph (1); and

3 “(II) not later than 12 months
4 after the date on which such final
5 order is issued, complete any hearing
6 under subparagraph (E).

7 “(ii) DISPUTE RESOLUTION RE-
8 QUEST.—The Secretary shall specify in an
9 interim final order issued under subpara-
10 graph (A) or (B) such shorter periods for
11 requesting dispute resolution under sub-
12 paragraph (D)(iii) as are necessary to
13 meet the requirements of this subpara-
14 graph.

15 “(G) JUDICIAL REVIEW.—A final order
16 issued pursuant to subparagraph (F) shall be
17 subject to judicial review in accordance with
18 paragraph (3)(D).

19 “(5) ADMINISTRATIVE ORDER INITIATED AT
20 THE REQUEST OF A REQUESTOR.—

21 “(A) IN GENERAL.—In issuing an adminis-
22 trative order under paragraph (1) at the re-
23 quest of a requestor with respect to certain
24 drugs, classes of drugs, or combinations of
25 drugs—

1 “(i) the Secretary shall, after receiv-
2 ing a request under this subparagraph, de-
3 termine whether the request is sufficiently
4 complete and formatted to permit a sub-
5 stantive review;

6 “(ii) if the Secretary determines that
7 the request is sufficiently complete and for-
8 matted to permit a substantive review, the
9 Secretary shall—

10 “(I) file the request; and

11 “(II) initiate proceedings with re-
12 spect to issuing an administrative
13 order in accordance with paragraphs
14 (2) and (3); and

15 “(iii) except as provided in paragraph
16 (6), if the Secretary determines that a re-
17 quest does not meet the requirements for
18 filing or is not sufficiently complete and
19 formatted to permit a substantive review,
20 the requestor may demand that the request
21 be filed over protest, and the Secretary
22 shall initiate proceedings to review the re-
23 quest in accordance with paragraph (2)(A).

24 “(B) REQUEST TO INITIATE PRO-
25 CEEDINGS.—

1 “(i) IN GENERAL.—A requestor seek-
2 ing an administrative order under para-
3 graph (1) with respect to certain drugs,
4 classes of drugs, or combinations of drugs,
5 shall submit to the Secretary a request to
6 initiate proceedings for such order in the
7 form and manner as specified by the Sec-
8 retary. Such requestor may submit a re-
9 quest under this subparagraph for the
10 issuance of an administrative order—

11 “(I) determining whether a drug
12 is generally recognized as safe and ef-
13 fective under section 201(p)(1), ex-
14 empt from section 503(b)(1), and not
15 required to be the subject of an ap-
16 proved application under section 505;
17 or

18 “(II) determining whether a
19 change to a condition of use of a drug
20 is generally recognized as safe and ef-
21 fective under section 201(p)(1), ex-
22 empt from section 503(b)(1), and not
23 required to be the subject of an ap-
24 proved application under section 505,

1 if, absent such a changed condition of
2 use, such drug is—

3 “(aa) generally recognized
4 as safe and effective under sec-
5 tion 201(p)(1) in accordance with
6 subsection (a)(1), (a)(2), or an
7 order under this subsection; or

8 “(bb) subject to subsection
9 (a)(3), but only if such requestor
10 initiates such request in conjunc-
11 tion with a request for the Sec-
12 retary to determine whether such
13 drug is generally recognized as
14 safe and effective under section
15 201(p)(1), which is filed by the
16 Secretary under subparagraph
17 (A)(ii).

18 “(ii) EXCEPTION.—The Secretary is
19 not required to complete review of a re-
20 quest for a change described in clause
21 (i)(II) if the Secretary determines that
22 there is an inadequate basis to find the
23 drug is generally recognized as safe and ef-
24 fective under section 201(p)(1) under para-

1 graph (1) and issues a final order an-
2 nouncing that determination.

3 “(iii) WITHDRAWAL.—The requestor
4 may withdraw a request under this para-
5 graph, according to the procedures set
6 forth pursuant to subsection (d)(2)(B).
7 Notwithstanding any other provision of
8 this section, if such request is withdrawn,
9 the Secretary may cease proceedings under
10 this subparagraph.

11 “(C) EXCLUSIVITY.—

12 “(i) IN GENERAL.—A final adminis-
13 trative order issued in response to a re-
14 quest under this section shall have the ef-
15 fect of authorizing solely the order re-
16 questor (or the licensees, assignees, or suc-
17 cessors in interest of such requestor with
18 respect to the subject of such order), for a
19 period of 18 months following the effective
20 date of such final order and beginning on
21 the date the requestor may lawfully market
22 such drugs pursuant to the order, to mar-
23 ket drugs—

24 “(I) incorporating changes de-
25 scribed in clause (ii); and

1 “(II) subject to the limitations
2 under clause (iv).

3 “(ii) CHANGES DESCRIBED.—A
4 change described in this clause is a change
5 subject to an order specified in clause (i),
6 which—

7 “(I) provides for a drug to con-
8 tain an active ingredient (including
9 any ester or salt of the active ingre-
10 dient) not previously incorporated in a
11 drug described in clause (iii); or

12 “(II) provides for a change in the
13 conditions of use of a drug, for which
14 new human data studies conducted or
15 sponsored by the requestor (or for
16 which the requestor has an exclusive
17 right of reference) were essential to
18 the issuance of such order.

19 “(iii) DRUGS DESCRIBED.—The drugs
20 described in this clause are drugs—

21 “(I) specified in subsection
22 (a)(1), (a)(2), or (a)(3);

23 “(II) subject to a final order
24 issued under this section;

1 “(III) subject to a final sun-
2 screen order (as defined in section
3 586(2)(A)); or

4 “(IV) described in subsection
5 (m)(1), other than drugs subject to an
6 active enforcement action under chap-
7 ter III of this Act.

8 “(iv) LIMITATIONS ON EXCLU-
9 SIVITY.—

10 “(I) IN GENERAL.—Only one 18-
11 month period under this subpara-
12 graph shall be granted, under each
13 order described in clause (i), with re-
14 spect to changes (to the drug subject
15 to such order) which are either—

16 “(aa) changes described in
17 clause (ii)(I), relating to active
18 ingredients; or

19 “(bb) changes described in
20 clause (ii)(II), relating to condi-
21 tions of use.

22 “(II) NO EXCLUSIVITY AL-
23 LOWED.—No exclusivity shall apply to
24 changes to a drug which are—

444

1 “(aa) the subject of a Tier 2
2 OTC monograph order request
3 (as defined in section 744L);

4 “(bb) safety-related changes,
5 as defined by the Secretary, or
6 any other changes the Secretary
7 considers necessary to assure
8 safe use; or

9 “(cc) changes related to
10 methods of testing safety or effi-
11 cacy.

12 “(v) NEW HUMAN DATA STUDIES DE-
13 FINED.—In this subparagraph, the term
14 ‘new human data studies’ means clinical
15 trials of safety or effectiveness (including
16 actual use studies), pharmacokinetics stud-
17 ies, or bioavailability studies, the results of
18 which—

19 “(I) have not been relied on by
20 the Secretary to support—

21 “(aa) a proposed or final de-
22 termination that a drug described
23 in subclause (I), (II), or (III) of
24 clause (iii) is generally recognized

445

1 as safe and effective under sec-
2 tion 201(p)(1); or

3 “(bb) approval of a drug
4 that was approved under section
5 505; and

6 “(II) do not duplicate the results
7 of another study that was relied on by
8 the Secretary to support—

9 “(aa) a proposed or final de-
10 termination that a drug described
11 in subclause (I), (II), or (III) of
12 clause (iii) is generally recognized
13 as safe and effective under sec-
14 tion 201(p)(1); or

15 “(bb) approval of a drug
16 that was approved under section
17 505.

18 “(vi) NOTIFICATION OF DRUG NOT
19 AVAILABLE FOR SALE.—A requestor that
20 is granted exclusivity with respect to a
21 drug under this subparagraph shall notify
22 the Secretary in writing within 1 year of
23 the issuance of the final administrative
24 order if the drug that is the subject of
25 such order will not be available for sale

1 within 1 year of the date of issuance of
2 such order. The requestor shall include
3 with such notice the—

4 “(I) identity of the drug by es-
5 tablished name and by proprietary
6 name, if any;

7 “(II) strength of the drug;

8 “(III) date on which the drug
9 will be available for sale, if known;
10 and

11 “(IV) reason for not marketing
12 the drug after issuance of the order.

13 “(6) INFORMATION REGARDING SAFE NON-
14 PRESCRIPTION MARKETING AND USE AS CONDITION
15 FOR FILING A GENERALLY RECOGNIZED AS SAFE
16 AND EFFECTIVE REQUEST.—

17 “(A) IN GENERAL.—In response to a re-
18 quest under this section that a drug described
19 in subparagraph (B) be generally recognized as
20 safe and effective, the Secretary—

21 “(i) may file such request, if the re-
22 quest includes information specified under
23 subparagraph (C) with respect to safe non-
24 prescription marketing and use of such
25 drug; or

1 “(ii) if the request fails to include in-
2 formation specified under subparagraph
3 (C), shall refuse to file such request and
4 require that nonprescription marketing of
5 the drug be pursuant to a new drug appli-
6 cation as described in subparagraph (D).

7 “(B) DRUG DESCRIBED.—A drug de-
8 scribed in this subparagraph is a nonprescrip-
9 tion drug which contains an active ingredient
10 not previously incorporated in a drug—

11 “(i) specified in subsection (a)(1),
12 (a)(2), or (a)(3);

13 “(ii) subject to a final order under
14 this section; or

15 “(iii) subject to a final sunscreen
16 order (as defined in section 586(2)(A)).

17 “(C) INFORMATION DEMONSTRATING
18 PRIMA FACIE SAFE NONPRESCRIPTION MAR-
19 KETING AND USE.—Information specified in
20 this subparagraph, with respect to a request de-
21 scribed in subparagraph (A)(i), is—

22 “(i) information sufficient for a prima
23 facie demonstration that the drug subject
24 to such request has a verifiable history of
25 being marketed and safely used by con-

1 sumers in the United States as a non-
2 prescription drug under comparable condi-
3 tions of use;

4 “(ii) if the drug has not been pre-
5 viously marketed in the United States as a
6 nonprescription drug, information suffi-
7 cient for a prima facie demonstration that
8 the drug was marketed and safely used
9 under comparable conditions of marketing
10 and use in a country listed in section
11 802(b)(1)(A) or designated by the Sec-
12 retary in accordance with section
13 802(b)(1)(B)—

14 “(I) for such period as needed to
15 provide reasonable assurances con-
16 cerning the safe nonprescription use
17 of the drug; and

18 “(II) during such time was sub-
19 ject to sufficient monitoring by a reg-
20 ulatory body considered acceptable by
21 the Secretary for such monitoring
22 purposes, including for adverse events
23 associated with nonprescription use of
24 the drug; or

1 “(iii) if the Secretary determines that
2 information described in clause (i) or (ii) is
3 not needed to provide a prima facie dem-
4 onstration that the drug can be safely mar-
5 keted and used as a nonprescription drug,
6 such other information the Secretary deter-
7 mines is sufficient for such purposes.

8 “(D) MARKETING PURSUANT TO NEW
9 DRUG APPLICATION.—In the case of a request
10 described in subparagraph (A)(ii), the drug
11 subject to such request may be resubmitted for
12 filing only if—

13 “(i) the drug is marketed as a non-
14 prescription drug, under conditions of use
15 comparable to the conditions specified in
16 the request, for such period as the Sec-
17 retary determines appropriate (not to ex-
18 ceed 5 consecutive years) pursuant to an
19 application approved under section 505;
20 and

21 “(ii) during such period, 1,000,000
22 retail packages of the drug, or an equiva-
23 lent quantity as determined by the Sec-
24 retary, were distributed for retail sale, as

1 determined in such manner as the Sec-
2 retary finds appropriate.

3 “(E) RULE OF APPLICATION.—Except in
4 the case of a request involving a drug described
5 in section 586(9), as in effect on January 1,
6 2017, if the Secretary refuses to file a request
7 under this paragraph, the requestor may not
8 file such request over protest under paragraph
9 (5)(A)(iii).

10 “(7) PACKAGING.—An administrative order
11 issued under paragraph (2), (4)(A), or (5) may in-
12 clude requirements for the packaging of a drug to
13 encourage use in accordance with labeling. Such re-
14 quirements may include unit dose packaging, re-
15 quirements for products intended for use by pedi-
16 atric populations, requirements to reduce risk of
17 harm from unsupervised ingestion, and other appro-
18 priate requirements. This paragraph does not au-
19 thorize the Food and Drug Administration to re-
20 quire standards or testing procedures as described in
21 part 1700 of title 16, Code of Federal Regulations.

22 “(8) FINAL AND TENTATIVE FINAL MONO-
23 GRAPHS FOR CATEGORY I DRUGS DEEMED FINAL
24 ADMINISTRATIVE ORDERS.—

1 “(A) IN GENERAL.—A final monograph or
2 tentative final monograph described in subpara-
3 graph (B) shall be deemed to be a final admin-
4 istrative order under this subsection and may
5 be amended, revoked, or otherwise modified in
6 accordance with the procedures of this sub-
7 section.

8 “(B) MONOGRAPHS DESCRIBED.—For pur-
9 poses of subparagraph (A), a final monograph
10 or tentative final monograph is described in this
11 subparagraph if it—

12 “(i) establishes conditions of use for a
13 drug described in paragraph (1) or (2) of
14 subsection (a); and

15 “(ii) represents the most recently pro-
16 mulgated version of such conditions, in-
17 cluding as modified, in whole or in part, by
18 any proposed or final rule.

19 “(C) DEEMED ORDERS INCLUDE HARMO-
20 NIZING TECHNICAL AMENDMENTS.—The
21 deemed establishment of a final administrative
22 order under subparagraph (A) shall be con-
23 strued to include any technical amendments to
24 such order as the Secretary determines nec-
25 essary to ensure that such order is appro-

1 priately harmonized, in terms of terminology or
2 cross-references, with the applicable provisions
3 of this Act (and regulations thereunder) and
4 any other orders issued under this section.

5 “(c) PROCEDURE FOR MINOR CHANGES.—

6 “(1) IN GENERAL.—Minor changes in the dos-
7 age form of a drug that is described in paragraph
8 (1) or (2) of subsection (a) or the subject of an
9 order issued under subsection (b) may be made by
10 a requestor without the issuance of an order under
11 subsection (b) if—

12 “(A) the requestor maintains such infor-
13 mation as is necessary to demonstrate that the
14 change—

15 “(i) will not affect the safety or effec-
16 tiveness of the drug; and

17 “(ii) will not materially affect the ex-
18 tent of absorption or other exposure to the
19 active ingredient in comparison to a suit-
20 able reference product; and

21 “(B) the change is in conformity with the
22 requirements of an applicable administrative
23 order issued by the Secretary under paragraph
24 (3).

25 “(2) ADDITIONAL INFORMATION.—

1 “(A) ACCESS TO RECORDS.—A sponsor
2 shall submit records requested by the Secretary
3 relating to such a minor change under section
4 704(a)(4), within 15 business days of receiving
5 such a request, or such longer period as the
6 Secretary may provide.

7 “(B) INSUFFICIENT INFORMATION.—If the
8 Secretary determines that the information con-
9 tained in such records is not sufficient to dem-
10 onstrate that the change does not affect the
11 safety or effectiveness of the drug or materially
12 affect the extent of absorption or other expo-
13 sure to the active ingredient, the Secretary—

14 “(i) may so inform the sponsor of the
15 drug in writing; and

16 “(ii) if the Secretary so informs the
17 sponsor, shall provide the sponsor of the
18 drug with a reasonable opportunity to pro-
19 vide additional information.

20 “(C) FAILURE TO SUBMIT SUFFICIENT IN-
21 FORMATION.—If the sponsor fails to provide
22 such additional information within a time pre-
23 scribed by the Secretary, or if the Secretary de-
24 termines that such additional information does
25 not demonstrate that the change does not—

1 “(i) affect the safety or effectiveness
2 of the drug; or

3 “(ii) materially affect the extent of
4 absorption or other exposure to the active
5 ingredient in comparison to a suitable ref-
6 erence product,

7 the drug as modified is a new drug under sec-
8 tion 201(p) and shall be deemed to be mis-
9 branded under section 502(ee).

10 “(3) DETERMINING WHETHER A CHANGE WILL
11 AFFECT SAFETY OR EFFECTIVENESS.—

12 “(A) IN GENERAL.—The Secretary shall
13 issue one or more administrative orders speci-
14 fying requirements for determining whether a
15 minor change made by a sponsor pursuant to
16 this subsection will affect the safety or effective-
17 ness of a drug or materially affect the extent of
18 absorption or other exposure to an active ingre-
19 dient in the drug in comparison to a suitable
20 reference product, together with guidance for
21 applying those orders to specific dosage forms.

22 “(B) STANDARD PRACTICES.—The orders
23 and guidance issued by the Secretary under
24 subparagraph (A) shall take into account rel-
25 evant public standards and standard practices

1 for evaluating the quality of drugs, and may
2 take into account the special needs of popu-
3 lations, including children.

4 “(d) CONFIDENTIALITY OF INFORMATION SUB-
5 MITTED TO THE SECRETARY.—

6 “(1) IN GENERAL.—Subject to paragraph (2),
7 any information, including reports of testing con-
8 ducted on the drug or drugs involved, that is sub-
9 mitted by a requestor in connection with proceedings
10 on an order under this section (including any minor
11 change under subsection (c)) and is a trade secret
12 or confidential information subject to section
13 552(b)(4) of title 5, United States Code, or section
14 1905 of title 18, United States Code, shall not be
15 disclosed to the public unless the requestor consents
16 to that disclosure.

17 “(2) PUBLIC AVAILABILITY.—

18 “(A) IN GENERAL.—Except as provided in
19 subparagraph (B), the Secretary shall—

20 “(i) make any information submitted
21 by a requestor in support of a request
22 under subsection (b)(5)(A) available to the
23 public not later than the date on which the
24 proposed order is issued; and

1 “(ii) make any information submitted
2 by any other person with respect to an
3 order requested (or initiated by the Sec-
4 retary) under subsection (b), available to
5 the public upon such submission.

6 “(B) LIMITATIONS ON PUBLIC AVAIL-
7 ABILITY.—Information described in subpara-
8 graph (A) shall not be made public if—

9 “(i) the information pertains to phar-
10 maceutical quality information, unless such
11 information is necessary to establish stand-
12 ards under which a drug is generally rec-
13 ognized as safe and effective under section
14 201(p)(1);

15 “(ii) the information is submitted in a
16 requestor-initiated request, but the re-
17 questor withdraws such request, in accord-
18 ance with withdrawal procedures estab-
19 lished by the Secretary, before the Sec-
20 retary issues the proposed order;

21 “(iii) the Secretary requests and ob-
22 tains the information under subsection (c)
23 and such information is not submitted in
24 relation to an order under subsection (b);
25 or

1 “(iv) the information is of the type
2 contained in raw datasets.

3 “(e) UPDATES TO DRUG LISTING INFORMATION.—
4 A sponsor who makes a change to a drug subject to this
5 section shall submit updated drug listing information for
6 the drug in accordance with section 510(j) within 30 cal-
7 endar days of the date when the drug is first commercially
8 marketed, except that a sponsor who was the order re-
9 questor with respect to an order subject to subsection
10 (b)(5)(C) (or a licensee, assignee, or successor in interest
11 of such requestor) shall submit updated drug listing infor-
12 mation on or before the date when the drug is first com-
13 mercially marketed.

14 “(f) APPROVALS UNDER SECTION 505.—The provi-
15 sions of this section shall not be construed to preclude a
16 person from seeking or maintaining the approval of an ap-
17 plication for a drug under sections 505(b)(1), 505(b)(2),
18 and 505(j). A determination under this section that a drug
19 is not subject to section 503(b)(1), is generally recognized
20 as safe and effective under section 201(p)(1), and is not
21 a new drug under section 201(p) shall constitute a finding
22 that the drug is safe and effective that may be relied upon
23 for purposes of an application under section 505(b)(2), so
24 that the applicant shall be required to submit for purposes
25 of such application only information needed to support any

1 modification of the drug that is not covered by such deter-
2 mination under this section.

3 “(g) PUBLIC AVAILABILITY OF ADMINISTRATIVE OR-
4 DERS.—The Secretary shall establish, maintain, update
5 (as determined necessary by the Secretary but no less fre-
6 quently than annually), and make publicly available, with
7 respect to orders issued under this section—

8 “(1) a repository of each final order and in-
9 terim final order in effect, including the complete
10 text of the order; and

11 “(2) a listing of all orders proposed and under
12 development under subsection (b)(2), including—

13 “(A) a brief description of each such order;
14 and

15 “(B) the Secretary’s expectations, if re-
16 sources permit, for issuance of proposed orders
17 over a 3-year period.

18 “(h) DEVELOPMENT ADVICE TO SPONSORS OR RE-
19 QUESTORS.—The Secretary shall establish procedures
20 under which sponsors or requestors may meet with appro-
21 priate officials of the Food and Drug Administration to
22 obtain advice on the studies and other information nec-
23 essary to support submissions under this section and other
24 matters relevant to the regulation of nonprescription

1 drugs and the development of new nonprescription drugs
2 under this section.

3 “(i) PARTICIPATION OF MULTIPLE SPONSORS OR RE-
4 QUESTORS.—The Secretary shall establish procedures to
5 facilitate efficient participation by multiple sponsors or re-
6 questors in proceedings under this section, including provi-
7 sion for joint meetings with multiple sponsors or reques-
8 tors or with organizations nominated by sponsors or re-
9 questors to represent their interests in a proceeding.

10 “(j) ELECTRONIC FORMAT.—All submissions under
11 this section shall be in electronic format.

12 “(k) EFFECT ON EXISTING REGULATIONS GOV-
13 ERNING NONPRESCRIPTION DRUGS.—

14 “(1) REGULATIONS OF GENERAL APPLICA-
15 BILITY TO NONPRESCRIPTION DRUGS.—Except as
16 provided in this subsection, nothing in this section
17 supersedes regulations establishing general require-
18 ments for nonprescription drugs, including regula-
19 tions of general applicability contained in parts 201,
20 250, and 330 of title 21, Code of Federal Regula-
21 tions, or any successor regulations. The Secretary
22 shall establish or modify such regulations by means
23 of rulemaking in accordance with section 553 of title
24 5, United States Code.

1 “(2) REGULATIONS ESTABLISHING REQUIRE-
2 MENTS FOR SPECIFIC NONPRESCRIPTION DRUGS.—

3 “(A) The provisions of section 310.545 of
4 title 21, Code of Federal Regulations, as in ef-
5 fect on the day before the date of the enact-
6 ment of this section, shall be deemed to be a
7 final order under subsection (b).

8 “(B) Regulations in effect on the day be-
9 fore the date of the enactment of this section,
10 establishing requirements for specific non-
11 prescription drugs marketed pursuant to this
12 section (including such requirements in parts
13 201 and 250 of title 21, Code of Federal Regu-
14 lations), shall be deemed to be final orders
15 under subsection (b), only as they apply to
16 drugs—

17 “(i) subject to paragraph (1), (2), (3),
18 or (4) of subsection (a); or

19 “(ii) otherwise subject to an order
20 under this section.

21 “(3) WITHDRAWAL OF REGULATIONS.—The
22 Secretary shall withdraw regulations establishing
23 final monographs and the procedures governing the
24 over-the-counter drug review under part 330 and
25 other relevant parts of title 21, Code of Federal

1 Regulations (as in effect on the day before the date
2 of the enactment of this section), or make technical
3 changes to such regulations to ensure conformity
4 with appropriate terminology and cross references.
5 Notwithstanding subchapter II of chapter 5 of title
6 5, United States Code, any such withdrawal or tech-
7 nical changes shall be made without public notice
8 and comment and shall be effective upon publication
9 through notice in the Federal Register (or upon such
10 date as specified in such notice).

11 “(1) GUIDANCE.—The Secretary shall issue guidance
12 that specifies—

13 “(1) the procedures and principles for formal
14 meetings between the Secretary and sponsors or re-
15 questors for drugs subject to this section;

16 “(2) the format and content of data submis-
17 sions to the Secretary under this section;

18 “(3) the format of electronic submissions to the
19 Secretary under this section;

20 “(4) consolidated proceedings for appeal and
21 the procedures for such proceedings where appro-
22 priate; and

23 “(5) for minor changes in drugs, recommenda-
24 tions on how to comply with the requirements in or-
25 ders issued under subsection (c)(3).

1 “(m) RULE OF CONSTRUCTION.—

2 “(1) IN GENERAL.—This section shall not af-
3 fect the treatment or status of a nonprescription
4 drug—

5 “(A) that is marketed without an applica-
6 tion approved under section 505 as of the date
7 of the enactment of this section;

8 “(B) that is not subject to an order issued
9 under this section; and

10 “(C) to which paragraph (1), (2), (3), (4),
11 or (5) of subsection (a) do not apply.

12 “(2) TREATMENT OF PRODUCTS PREVIOUSLY
13 FOUND TO BE SUBJECT TO TIME AND EXTENT RE-
14 QUIREMENTS.—

15 “(A) Notwithstanding subsection (a), a
16 drug described in subparagraph (B) may only
17 be lawfully marketed, without an application
18 approved under section 505, pursuant to an
19 order issued under this section.

20 “(B) A drug described in this subpara-
21 graph is a drug which, prior to the date of the
22 enactment of this section, the Secretary deter-
23 mined in a proposed or final rule to be ineligible
24 for review under the OTC drug review (as such
25 phrase ‘OTC drug review’ was used in section

1 330.14 of title 21, Code of Federal Regulations,
2 as in effect on the day before the date of the
3 enactment of this section).

4 “(3) PRESERVATION OF AUTHORITY.—

5 “(A) Nothing in paragraph (1) shall be
6 construed to preclude or limit the applicability
7 of any provision of this Act other than this sec-
8 tion.

9 “(B) Nothing in subsection (a) shall be
10 construed to prohibit the Secretary from issuing
11 an order under this section finding a drug to be
12 not generally recognized as safe and effective
13 under section 201(p)(1), as the Secretary deter-
14 mines appropriate.

15 “(n) INVESTIGATIONAL NEW DRUGS.—A drug is not
16 subject to this section if an exemption for investigational
17 use under section 505(i) is in effect for such drug.

18 “(o) INAPPLICABILITY OF PAPERWORK REDUCTION
19 ACT.—Chapter 35 of title 44, United States Code, shall
20 not apply to collections of information made under this
21 section.

22 “(p) INAPPLICABILITY OF NOTICE AND COMMENT
23 RULEMAKING AND OTHER REQUIREMENTS.—The re-
24 quirements of subsection (b) shall apply with respect to
25 orders issued under this section instead of the require-

1 ments of subchapter II of chapter 5 of title 5, United
2 States Code.

3 “(q) DEFINITIONS.—In this section:

4 “(1) The term ‘nonprescription drug’ refers to
5 a drug not subject to the requirements of section
6 503(b)(1).

7 “(2) The term ‘sponsor’ refers to any person
8 marketing, manufacturing, or processing a drug
9 that—

10 “(A) is listed pursuant to section 510(j);

11 and

12 “(B) is or will be subject to an administra-
13 tive order under this section of the Food and
14 Drug Administration.

15 “(3) The term ‘requestor’ refers to any person
16 or group of persons marketing, manufacturing, proc-
17 essing, or developing a drug.”.

18 (b) GAO STUDY.—Not later than 4 years after the
19 date of enactment of this Act, the Comptroller General
20 of the United States shall submit a study to the Com-
21 mittee on Energy and Commerce of the House of Rep-
22 resentatives and the Committee on Health, Education,
23 Labor, and Pensions of the Senate addressing the effec-
24 tiveness and overall impact of exclusivity under section
25 505G of the Federal Food, Drug, and Cosmetic Act, as

1 added by subsection (a), and section 586C of such Act
2 (21 U.S.C. 360fff-3), including the impact of such exclu-
3 sivity on consumer access. Such study shall include—

4 (1) an analysis of the impact of exclusivity
5 under such section 505G for nonprescription drug
6 products, including—

7 (A) the number of nonprescription drug
8 products that were granted exclusivity and the
9 indication for which the nonprescription drug
10 products were determined to be generally recog-
11 nized as safe and effective;

12 (B) whether the exclusivity for such drug
13 products was granted for—

14 (i) a new active ingredient (including
15 any ester or salt of the active ingredient);

16 or

17 (ii) changes in the conditions of use of
18 a drug, for which new human data studies
19 conducted or sponsored by the requestor
20 were essential;

21 (C) whether, and to what extent, the exclu-
22 sivity impacted the requestor's or sponsor's de-
23 cision to develop the drug product;

1 (D) an analysis of the implementation of
2 the exclusivity provision in such section 505G,
3 including—

4 (i) the resources used by the Food
5 and Drug Administration;

6 (ii) the impact of such provision on
7 innovation, as well as research and devel-
8 opment in the nonprescription drug mar-
9 ket;

10 (iii) the impact of such provision on
11 competition in the nonprescription drug
12 market;

13 (iv) the impact of such provision on
14 consumer access to nonprescription drug
15 products;

16 (v) the impact of such provision on
17 the prices of nonprescription drug prod-
18 ucts; and

19 (vi) whether the administrative orders
20 initiated by requestors under such section
21 505G have been sufficient to encourage the
22 development of nonprescription drug prod-
23 ucts that would likely not be otherwise de-
24 veloped, or developed in as timely a man-
25 ner; and

1 (E) whether the administrative orders ini-
2 tiated by requestors under such section 505G
3 have been sufficient incentive to encourage in-
4 novation in the nonprescription drug market;
5 and

6 (2) an analysis of the impact of exclusivity
7 under such section 586C for sunscreen ingredients,
8 including—

9 (A) the number of sunscreen ingredients
10 that were granted exclusivity and the specific
11 ingredient that was determined to be generally
12 recognized as safe and effective;

13 (B) whether, and to what extent, the exclu-
14 sivity impacted the requestor's or sponsor's de-
15 cision to develop the sunscreen ingredient;

16 (C) whether, and to what extent, the sun-
17 screen ingredient granted exclusivity had pre-
18 viously been available outside of the United
19 States;

20 (D) an analysis of the implementation of
21 the exclusivity provision in such section 586C,
22 including—

23 (i) the resources used by the Food
24 and Drug Administration;

1 (ii) the impact of such provision on
2 innovation, as well as research and devel-
3 opment in the sunscreen market;

4 (iii) the impact of such provision on
5 competition in the sunscreen market;

6 (iv) the impact of such provision on
7 consumer access to sunscreen products;

8 (v) the impact of such provision on
9 the prices of sunscreen products; and

10 (vi) whether the administrative orders
11 initiated by requestors under such section
12 505G have been utilized by sunscreen in-
13 gredient sponsors and whether such proc-
14 ess has been sufficient to encourage the
15 development of sunscreen ingredients that
16 would likely not be otherwise developed, or
17 developed in as timely a manner; and

18 (E) whether the administrative orders ini-
19 tiated by requestors under such section 586C
20 have been sufficient incentive to encourage in-
21 novation in the sunscreen market.

22 (c) CONFORMING AMENDMENT.—Section 751(d)(1)
23 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
24 379r(d)(1)) is amended—

25 (1) in the matter preceding subparagraph (A)—

1 (A) by striking “final regulation promul-
2 gated” and inserting “final order under section
3 505G”; and

4 (B) by striking “and not misbranded”; and
5 (2) in subparagraph (A), by striking “regula-
6 tion in effect” and inserting “regulation or order in
7 effect”.

8 **SEC. 3852. MISBRANDING.**

9 Section 502 of the Federal Food, Drug, and Cosmetic
10 Act (21 U.S.C. 352) is amended by adding at the end the
11 following:

12 “(ee) If it is a nonprescription drug that is subject
13 to section 505G, is not the subject of an application ap-
14 proved under section 505, and does not comply with the
15 requirements under section 505G.

16 “(ff) If it is a drug and it was manufactured, pre-
17 pared, propagated, compounded, or processed in a facility
18 for which fees have not been paid as required by section
19 744M.”.

20 **SEC. 3853. DRUGS EXCLUDED FROM THE OVER-THE-**
21 **COUNTER DRUG REVIEW.**

22 (a) IN GENERAL.—Nothing in this Act (or the
23 amendments made by this Act) shall apply to any non-
24 prescription drug (as defined in section 505G(q) of the
25 Federal Food, Drug, and Cosmetic Act, as added by sec-

1 tion 3851 of this subtitle) which was excluded by the Food
2 and Drug Administration from the Over-the-Counter
3 Drug Review in accordance with the paragraph numbered
4 25 on page 9466 of volume 37 of the Federal Register,
5 published on May 11, 1972.

6 (b) **RULE OF CONSTRUCTION.**—Nothing in this sec-
7 tion shall be construed to preclude or limit the applica-
8 bility of any other provision of the Federal Food, Drug,
9 and Cosmetic Act (21 U.S.C. 301 et seq.).

10 **SEC. 3854. TREATMENT OF SUNSCREEN INNOVATION ACT.**

11 (a) **REVIEW OF NONPRESCRIPTION SUNSCREEN AC-**
12 **TIVE INGREDIENTS.**—

13 (1) **APPLICABILITY OF SECTION 505G FOR**
14 **PENDING SUBMISSIONS.**—

15 (A) **IN GENERAL.**—A sponsor of a non-
16 prescription sunscreen active ingredient or com-
17 bination of nonprescription sunscreen active in-
18 gredients that, as of the date of enactment of
19 this Act, is subject to a proposed sunscreen
20 order under section 586C of the Federal Food,
21 Drug, and Cosmetic Act (21 U.S.C. 360fff–3)
22 may elect, by means of giving written notifica-
23 tion to the Secretary of Health and Human
24 Services within 180 calendar days of the enact-
25 ment of this Act, to transition into the review

1 of such ingredient or combination of ingredients
2 pursuant to the process set out in section 505G
3 of the Federal Food, Drug, and Cosmetic Act,
4 as added by section 3851 of this subtitle.

5 (B) ELECTION EXERCISED.—Upon receipt
6 by the Secretary of Health and Human Services
7 of a timely notification under subparagraph
8 (A)—

9 (i) the proposed sunscreen order in-
10 volved is deemed to be a request for an
11 order under subsection (b) of section 505G
12 of the Federal Food, Drug, and Cosmetic
13 Act, as added by section 3851 of this sub-
14 title; and

15 (ii) such order is deemed to have been
16 accepted for filing under subsection
17 (b)(6)(A)(i) of such section 505G.

18 (C) ELECTION NOT EXERCISED.—If a noti-
19 fication under subparagraph (A) is not received
20 by the Secretary of Health and Human Services
21 within 180 calendar days of the date of enact-
22 ment of this Act, the review of the proposed
23 sunscreen order described in subparagraph
24 (A)—

1 (i) shall continue under section 586C
2 of the Federal Food, Drug, and Cosmetic
3 Act (21 U.S.C. 360fff–3); and

4 (ii) shall not be eligible for review
5 under section 505G, added by section 3851
6 of this subtitle.

7 (2) DEFINITIONS.—In this subsection, the
8 terms “sponsor”, “nonprescription”, “sunscreen ac-
9 tive ingredient”, and “proposed sunscreen order”
10 have the meanings given to those terms in section
11 586 of the Federal Food, Drug, and Cosmetic Act
12 (21 U.S.C. 360fff).

13 (b) AMENDMENTS TO SUNSCREEN PROVISIONS.—

14 (1) FINAL SUNSCREEN ORDERS.—Paragraph
15 (3) of section 586C(e) of the Federal Food, Drug,
16 and Cosmetic Act (21 U.S.C. 360fff–3(e)) is amend-
17 ed to read as follows:

18 “(3) RELATIONSHIP TO ORDERS UNDER SEC-
19 TION 505G.—A final sunscreen order shall be deemed
20 to be a final order under section 505G.”.

21 (2) MEETINGS.—Paragraph (7) of section
22 586C(b) of the Federal Food, Drug, and Cosmetic
23 Act (21 U.S.C. 360fff–3(b)) is amended—

24 (A) by striking “A sponsor may request”
25 and inserting the following:

1 “(A) IN GENERAL.—A sponsor may re-
2 quest”; and

3 (B) by adding at the end the following:

4 “(B) CONFIDENTIAL MEETINGS.—A spon-
5 sor may request one or more confidential meet-
6 ings with respect to a proposed sunscreen order,
7 including a letter deemed to be a proposed sun-
8 screen order under paragraph (3), to discuss
9 matters relating to data requirements to sup-
10 port a general recognition of safety and effec-
11 tiveness involving confidential information and
12 public information related to such proposed
13 sunscreen order, as appropriate. The Secretary
14 shall convene a confidential meeting with such
15 sponsor in a reasonable time period. If a spon-
16 sor requests more than one confidential meeting
17 for the same proposed sunscreen order, the Sec-
18 retary may refuse to grant an additional con-
19 fidential meeting request if the Secretary deter-
20 mines that such additional confidential meeting
21 is not reasonably necessary for the sponsor to
22 advance its proposed sunscreen order, or if the
23 request for a confidential meeting fails to in-
24 clude sufficient information upon which to base
25 a substantive discussion. The Secretary shall

1 publish a post-meeting summary of each con-
2 fidential meeting under this subparagraph that
3 does not disclose confidential commercial infor-
4 mation or trade secrets. This subparagraph
5 does not authorize the disclosure of confidential
6 commercial information or trade secrets subject
7 to 552(b)(4) of title 5, United States Code, or
8 section 1905 of title 18, United States Code.”.

9 (3) EXCLUSIVITY.—Section 586C of the Fed-
10 eral Food, Drug, and Cosmetic Act (21 U.S.C.
11 360fff-3) is amended by adding at the end the fol-
12 lowing:

13 “(f) EXCLUSIVITY.—

14 “(1) IN GENERAL.—A final sunscreen order
15 shall have the effect of authorizing solely the order
16 requestor (or the licensees, assignees, or successors
17 in interest of such requestor with respect to the sub-
18 ject of such request and listed under paragraph (5))
19 for a period of 18 months, to market a sunscreen in-
20 gredient under this section incorporating changes
21 described in paragraph (2) subject to the limitations
22 under paragraph (4), beginning on the date the re-
23 questor (or any licensees, assignees, or successors in
24 interest of such requestor with respect to the subject
25 of such request and listed under paragraph (5)) may

1 lawfully market such sunscreen ingredient pursuant
2 to the order.

3 “(2) CHANGES DESCRIBED.—A change de-
4 scribed in this paragraph is a change subject to an
5 order specified in paragraph (1) that permits a sun-
6 screen to contain an active sunscreen ingredient not
7 previously incorporated in a marketed sunscreen list-
8 ed in paragraph (3).

9 “(3) MARKETED SUNSCREEN.—The marketed
10 sunscreen ingredients described in this paragraph
11 are sunscreen ingredients—

12 “(A) marketed in accordance with a final
13 monograph for sunscreen drug products set
14 forth at part 352 of title 21, Code of Federal
15 Regulations (as published at 64 Fed. Reg.
16 27687); or

17 “(B) marketed in accordance with a final
18 order issued under this section.

19 “(4) LIMITATIONS ON EXCLUSIVITY.—Only one
20 18-month period may be granted per ingredient
21 under paragraph (1).

22 “(5) LISTING OF LICENSEES, ASSIGNEES, OR
23 SUCCESSORS IN INTEREST.—Requestors shall submit
24 to the Secretary at the time when a drug subject to
25 such request is introduced or delivered for introduc-

1 tion into interstate commerce, a list of licensees, as-
2 signees, or successors in interest under paragraph
3 (1).”.

4 (4) SUNSET PROVISION.—Subchapter I of chap-
5 ter V of the Federal Food, Drug, and Cosmetic Act
6 (21 U.S.C. 360fff et seq.) is amended by adding at
7 the end the following:

8 **“SEC. 586H. SUNSET.**

9 “This subchapter shall cease to be effective at the end
10 of fiscal year 2022.”.

11 (5) TREATMENT OF FINAL SUNSCREEN
12 ORDER.—The Federal Food, Drug, and Cosmetic
13 Act is amended by striking section 586E of such Act
14 (21 U.S.C. 360fff–5).

15 (c) TREATMENT OF AUTHORITY REGARDING FINAL-
16 IZATION OF SUNSCREEN MONOGRAPH.—

17 (1) IN GENERAL.—

18 (A) REVISION OF FINAL SUNSCREEN
19 ORDER.—The Secretary of Health and Human
20 Services (referred to in this subsection as the
21 “Secretary”) shall amend and revise the final
22 administrative order concerning nonprescription
23 sunscreen (referred to in this subsection as the
24 “sunscreen order”) for which the content, prior
25 to the date of enactment of this Act, was rep-

1 resented by the final monograph for sunscreen
2 drug products set forth in part 352 of title 21,
3 Code of Federal Regulations (as in effect on
4 May 21, 1999).

5 (B) ISSUANCE OF REVISED SUNSCREEN
6 ORDER; EFFECTIVE DATE.—A revised sunscreen
7 order described in subparagraph (A) shall be—

8 (i) issued in accordance with the pro-
9 cedures described in section 505G(b)(2) of
10 the Federal Food, Drug, and Cosmetic
11 Act;

12 (ii) issued in proposed form not later
13 than 18 months after the date of enact-
14 ment of this Act; and

15 (iii) issued by the Secretary at least 1
16 year prior to the effective date of the re-
17 vised order.

18 (2) REPORTS.—If a revised sunscreen order
19 issued under paragraph (1) does not include provi-
20 sions related to the effectiveness of various sun pro-
21 tection factor levels, and does not address all dosage
22 forms known to the Secretary to be used in sun-
23 screens marketed in the United States without a
24 new drug application approved under section 505 of
25 the Federal Food, Drug, and Cosmetic Act (21

1 U.S.C. 355), the Secretary shall submit a report to
2 the Committee on Energy and Commerce of the
3 House of Representatives and the Committee on
4 Health, Education, Labor, and Pensions of the Sen-
5 ate on the rationale for omission of such provisions
6 from such order, and a plan and timeline to compile
7 any information necessary to address such provisions
8 through such order.

9 (d) TREATMENT OF NON-SUNSCREEN TIME AND EX-
10 TENT APPLICATIONS.—

11 (1) IN GENERAL.—Any application described in
12 section 586F of the Federal Food, Drug, and Cos-
13 metic Act (21 U.S.C. 360fff-6) that was submitted
14 to the Secretary pursuant to section 330.14 of title
15 21, Code of Federal Regulations, as such provisions
16 were in effect immediately prior to the date of enact-
17 ment date of this Act, shall be extinguished as of
18 such date of enactment, subject to paragraph (2).

19 (2) ORDER REQUEST.—Nothing in paragraph
20 (1) precludes the submission of an order request
21 under section 505G(b) of the Federal Food, Drug,
22 and Cosmetic Act, as added by section 3851 of this
23 subtitle, with respect to a drug that was the subject
24 of an application extinguished under paragraph (1).

1 **SEC. 3855. ANNUAL UPDATE TO CONGRESS ON APPRO-**
2 **PRIATE PEDIATRIC INDICATION FOR CER-**
3 **TAIN OTC COUGH AND COLD DRUGS.**

4 (a) IN GENERAL.—Subject to subsection (c), the Sec-
5 retary of Health and Human Services shall, beginning not
6 later than 1 year after the date of enactment of this Act,
7 annually submit to the Committee on Energy and Com-
8 merce of the House of Representatives and the Committee
9 on Health, Education, Labor, and Pensions of the Senate
10 a letter describing the progress of the Food and Drug Ad-
11 ministration—

12 (1) in evaluating the cough and cold monograph
13 described in subsection (b) with respect to children
14 under age 6; and

15 (2) as appropriate, revising such cough and cold
16 monograph to address such children through the
17 order process under section 505G(b) of the Federal
18 Food, Drug, and Cosmetic Act, as added by section
19 3851 of this subtitle.

20 (b) COUGH AND COLD MONOGRAPH DESCRIBED.—
21 The cough and cold monograph described in this sub-
22 section consists of the conditions under which nonprescrip-
23 tion drugs containing antitussive, expectorant, nasal de-
24 congestant, or antihistamine active ingredients (or com-
25 binations thereof) are generally recognized as safe and ef-
26 fective, as specified in part 341 of title 21, Code of Federal

1 Regulations (as in effect immediately prior to the date of
2 enactment of this Act), and included in an order deemed
3 to be established under section 505G(b) of the Federal
4 Food, Drug, and Cosmetic Act, as added by section 3851
5 of this subtitle.

6 (c) DURATION OF AUTHORITY.—The requirement
7 under subsection (a) shall terminate as of the date of a
8 letter submitted by the Secretary of Health and Human
9 Services pursuant to such subsection in which the Sec-
10 retary indicates that the Food and Drug Administration
11 has completed its evaluation and revised, in a final order,
12 as applicable, the cough and cold monograph as described
13 in subsection (a)(2).

14 **SEC. 3856. TECHNICAL CORRECTIONS.**

15 (a) IMPORTS AND EXPORTS.—Section
16 801(e)(4)(E)(iii) of the Federal Food, Drug, and Cosmetic
17 Act (21 U.S.C. 381(e)(4)(E)(iii)) is amended by striking
18 “subparagraph” each place such term appears and insert-
19 ing “paragraph”.

20 (b) FDA REAUTHORIZATION ACT OF 2017.—

21 (1) IN GENERAL.—Section 905(b)(4) of the
22 FDA Reauthorization Act of 2017 (Public Law 115–
23 52) is amended by striking “Section 744H(e)(2)(B)”
24 and inserting “Section 744H(f)(2)(B)”.

1 (2) EFFECTIVE DATE.—The amendment made
2 by paragraph (1) shall take effect as of the enact-
3 ment of the FDA Reauthorization Act of 2017
4 (Public Law 115–52).

5 **PART II—USER FEES**

6 **SEC. 3861. FINDING.**

7 The Congress finds that the fees authorized by the
8 amendments made in this part will be dedicated to OTC
9 monograph drug activities, as set forth in the goals identi-
10 fied for purposes of part 10 of subchapter C of chapter
11 VII of the Federal Food, Drug, and Cosmetic Act, in the
12 letters from the Secretary of Health and Human Services
13 to the Chairman of the Committee on Health, Education,
14 Labor, and Pensions of the Senate and the Chairman of
15 the Committee on Energy and Commerce of the House
16 of Representatives, as set forth in the Congressional
17 Record.

18 **SEC. 3862. FEES RELATING TO OVER-THE-COUNTER DRUGS.**

19 Subchapter C of chapter VII of the Federal Food,
20 Drug, and Cosmetic Act (21 U.S.C. 379f et seq.) is
21 amended by inserting after part 9 the following:

22 **“PART 10—FEES RELATING TO OVER-THE-**
23 **COUNTER DRUGS**

24 **“SEC. 744L. DEFINITIONS.**

25 “In this part:

1 “(1) The term ‘affiliate’ means a business enti-
2 ty that has a relationship with a second business en-
3 tity if, directly or indirectly—

4 “(A) one business entity controls, or has
5 the power to control, the other business entity;
6 or

7 “(B) a third party controls, or has power
8 to control, both of the business entities.

9 “(2) The term ‘contract manufacturing organi-
10 zation facility’ means an OTC monograph drug facil-
11 ity where neither the owner of such manufacturing
12 facility nor any affiliate of such owner or facility
13 sells the OTC monograph drug produced at such fa-
14 cility directly to wholesalers, retailers, or consumers
15 in the United States.

16 “(3) The term ‘costs of resources allocated for
17 OTC monograph drug activities’ means the expenses
18 in connection with OTC monograph drug activities
19 for—

20 “(A) officers and employees of the Food
21 and Drug Administration, contractors of the
22 Food and Drug Administration, advisory com-
23 mittees, and costs related to such officers, em-
24 ployees, and committees and costs related to
25 contracts with such contractors;

1 “(B) management of information, and the
2 acquisition, maintenance, and repair of com-
3 puter resources;

4 “(C) leasing, maintenance, renovation, and
5 repair of facilities and acquisition, maintenance,
6 and repair of fixtures, furniture, scientific
7 equipment, and other necessary materials and
8 supplies; and

9 “(D) collecting fees under section 744M
10 and accounting for resources allocated for OTC
11 monograph drug activities.

12 “(4) The term ‘FDA establishment identifier’ is
13 the unique number automatically generated by Food
14 and Drug Administration’s Field Accomplishments
15 and Compliance Tracking System (FACTS) (or any
16 successor system).

17 “(5) The term ‘OTC monograph drug’ means a
18 nonprescription drug without an approved new drug
19 application which is governed by the provisions of
20 section 505G.

21 “(6) The term ‘OTC monograph drug activities’
22 means activities of the Secretary associated with
23 OTC monograph drugs and inspection of facilities
24 associated with such products, including the fol-
25 lowing activities:

1 “(A) The activities necessary for review
2 and evaluation of OTC monographs and OTC
3 monograph order requests, including—

4 “(i) orders proposing or finalizing ap-
5 plicable conditions of use for OTC mono-
6 graph drugs;

7 “(ii) orders affecting status regarding
8 general recognition of safety and effective-
9 ness of an OTC monograph ingredient or
10 combination of ingredients under specified
11 conditions of use;

12 “(iii) all OTC monograph drug devel-
13 opment and review activities, including
14 intra-agency collaboration;

15 “(iv) regulation and policy develop-
16 ment activities related to OTC monograph
17 drugs;

18 “(v) development of product standards
19 for products subject to review and evalua-
20 tion;

21 “(vi) meetings referred to in section
22 505G(i);

23 “(vii) review of labeling prior to
24 issuance of orders related to OTC mono-
25 graph drugs or conditions of use; and

1 “(viii) regulatory science activities re-
2 lated to OTC monograph drugs.

3 “(B) Inspections related to OTC mono-
4 graph drugs.

5 “(C) Monitoring of clinical and other re-
6 search conducted in connection with OTC
7 monograph drugs.

8 “(D) Safety activities with respect to OTC
9 monograph drugs, including—

10 “(i) collecting, developing, and review-
11 ing safety information on OTC monograph
12 drugs, including adverse event reports;

13 “(ii) developing and using improved
14 adverse event data-collection systems, in-
15 cluding information technology systems;
16 and

17 “(iii) developing and using improved
18 analytical tools to assess potential safety
19 risks, including access to external data-
20 bases.

21 “(E) Other activities necessary for imple-
22 mentation of section 505G.

23 “(7) The term ‘OTC monograph order request’
24 means a request for an order submitted under sec-
25 tion 505G(b)(5).

1 “(8) The term ‘Tier 1 OTC monograph order
2 request’ means any OTC monograph order request
3 not determined to be a Tier 2 OTC monograph
4 order request.

5 “(9)(A) The term ‘Tier 2 OTC monograph
6 order request’ means, subject to subparagraph (B),
7 an OTC monograph order request for—

8 “(i) the reordering of existing information
9 in the drug facts label of an OTC monograph
10 drug;

11 “(ii) the addition of information to the
12 other information section of the drug facts label
13 of an OTC monograph drug, as limited by sec-
14 tion 201.66(c)(7) of title 21, Code of Federal
15 Regulations (or any successor regulations);

16 “(iii) modification to the directions for use
17 section of the drug facts label of an OTC mono-
18 graph drug, if such changes conform to changes
19 made pursuant to section 505G(c)(3)(A);

20 “(iv) the standardization of the concentra-
21 tion or dose of a specific finalized ingredient
22 within a particular finalized monograph;

23 “(v) a change to ingredient nomenclature
24 to align with nomenclature of a standards-set-
25 ting organization; or

1 “(vi) addition of an interchangeable term
2 in accordance with section 330.1 of title 21,
3 Code of Federal Regulations (or any successor
4 regulations).

5 “(B) The Secretary may, based on program im-
6 plementation experience or other factors found ap-
7 propriate by the Secretary, characterize any OTC
8 monograph order request as a Tier 2 OTC mono-
9 graph order request (including recharacterizing a re-
10 quest from Tier 1 to Tier 2) and publish such deter-
11 mination in a proposed order issued pursuant to sec-
12 tion 505G.

13 “(10)(A) The term ‘OTC monograph drug facil-
14 ity’ means a foreign or domestic business or other
15 entity that—

16 “(i) is—

17 “(I) under one management, either di-
18 rect or indirect; and

19 “(II) at one geographic location or ad-
20 dress engaged in manufacturing or proc-
21 essing the finished dosage form of an OTC
22 monograph drug;

23 “(ii) includes a finished dosage form man-
24 ufacturer facility in a contractual relationship
25 with the sponsor of one or more OTC mono-

1 graph drugs to manufacture or process such
2 drugs; and

3 “(iii) does not include a business or other
4 entity whose only manufacturing or processing
5 activities are one or more of the following: pro-
6 duction of clinical research supplies, testing, or
7 placement of outer packaging on packages con-
8 taining multiple products, for such purposes as
9 creating multipacks, when each monograph
10 drug product contained within the overpack-
11 aging is already in a final packaged form prior
12 to placement in the outer overpackaging.

13 “(B) For purposes of subparagraph (A)(i)(II),
14 separate buildings or locations within close proximity
15 are considered to be at one geographic location or
16 address if the activities conducted in such buildings
17 or locations are—

18 “(i) closely related to the same business
19 enterprise;

20 “(ii) under the supervision of the same
21 local management; and

22 “(iii) under a single FDA establishment
23 identifier and capable of being inspected by the
24 Food and Drug Administration during a single
25 inspection.

1 “(C) If a business or other entity would meet
2 criteria specified in subparagraph (A), but for being
3 under multiple management, the business or other
4 entity is deemed to constitute multiple facilities, one
5 per management entity, for purposes of this para-
6 graph.

7 “(11) The term ‘OTC monograph drug meet-
8 ing’ means any meeting regarding the content of a
9 proposed OTC monograph order request.

10 “(12) The term ‘person’ includes an affiliate of
11 a person.

12 “(13) The terms ‘requestor’ and ‘sponsor’ have
13 the meanings given such terms in section 505G.

14 **“SEC. 744M. AUTHORITY TO ASSESS AND USE OTC MONO-**
15 **GRAPH FEES.**

16 “(a) TYPES OF FEES.—Beginning with fiscal year
17 2021, the Secretary shall assess and collect fees in accord-
18 ance with this section as follows:

19 “(1) FACILITY FEE.—

20 “(A) IN GENERAL.—Each person that
21 owns a facility identified as an OTC monograph
22 drug facility on December 31 of the fiscal year
23 or at any time during the preceding 12-month
24 period shall be assessed an annual fee for each

1 such facility as determined under subsection
2 (e).

3 “(B) EXCEPTIONS.—

4 “(i) FACILITIES THAT CEASE ACTIVI-
5 TIES.—A fee shall not be assessed under
6 subparagraph (A) if the identified OTC
7 monograph drug facility—

8 “(I) has ceased all activities re-
9 lated to OTC monograph drugs prior
10 to December 31 of the year imme-
11 diately preceding the applicable fiscal
12 year; and

13 “(II) has updated its registration
14 to reflect such change under the re-
15 quirements for drug establishment
16 registration set forth in section 510.

17 “(ii) CONTRACT MANUFACTURING OR-
18 GANIZATIONS.—The amount of the fee for
19 a contract manufacturing organization fa-
20 cility shall be equal to two-thirds of the
21 amount of the fee for an OTC monograph
22 drug facility that is not a contract manu-
23 facturing organization facility.

1 “(C) AMOUNT.—The amount of fees estab-
2 lished under subparagraph (A) shall be estab-
3 lished under subsection (c).

4 “(D) DUE DATE.—

5 “(i) FOR FIRST PROGRAM YEAR.—For
6 fiscal year 2021, the facility fees required
7 under subparagraph (A) shall be due on
8 the later of—

9 “(I) the first business day of
10 July of 2020; or

11 “(II) 45 calendar days after pub-
12 lication of the Federal Register notice
13 provided for under subsection
14 (c)(4)(A).

15 “(ii) SUBSEQUENT FISCAL YEARS.—
16 For each fiscal year after fiscal year 2021,
17 the facility fees required under subpara-
18 graph (A) shall be due on the later of—

19 “(I) the first business day of
20 June of such year; or

21 “(II) the first business day after
22 the enactment of an appropriations
23 Act providing for the collection and
24 obligation of fees under this section
25 for such year.

1 “(2) OTC MONOGRAPH ORDER REQUEST
2 FEE.—

3 “(A) IN GENERAL.—Each person that sub-
4 mits an OTC monograph order request shall be
5 subject to a fee for an OTC monograph order
6 request. The amount of such fee shall be—

7 “(i) for a Tier 1 OTC monograph
8 order request, \$500,000, adjusted for in-
9 flation for the fiscal year (as determined
10 under subsection (c)(1)(B)); and

11 “(ii) for a Tier 2 OTC monograph
12 order request, \$100,000, adjusted for in-
13 flation for the fiscal year (as determined
14 under subsection (c)(1)(B)).

15 “(B) DUE DATE.—The OTC monograph
16 order request fees required under subparagraph
17 (A) shall be due on the date of submission of
18 the OTC monograph order request.

19 “(C) EXCEPTION FOR CERTAIN SAFETY
20 CHANGES.—A person who is named as the re-
21 questor in an OTC monograph order shall not
22 be subject to a fee under subparagraph (A) if
23 the Secretary finds that the OTC monograph
24 order request seeks to change the drug facts la-

1 belong of an OTC monograph drug in a way
2 that would add to or strengthen—

3 “(i) a contraindication, warning, or
4 precaution;

5 “(ii) a statement about risk associated
6 with misuse or abuse; or

7 “(iii) an instruction about dosage and
8 administration that is intended to increase
9 the safe use of the OTC monograph drug.

10 “(D) REFUND OF FEE IF ORDER REQUEST
11 IS RECATEGORIZED AS A TIER 2 OTC MONO-
12 GRAPH ORDER REQUEST.—If the Secretary de-
13 termines that an OTC monograph request ini-
14 tially characterized as Tier 1 shall be re-charac-
15 terized as a Tier 2 OTC monograph order re-
16 quest, and the requestor has paid a Tier 1 fee
17 in accordance with subparagraph (A)(i), the
18 Secretary shall refund the requestor the dif-
19 ference between the Tier 1 and Tier 2 fees de-
20 termined under subparagraphs (A)(i) and
21 (A)(ii), respectively.

22 “(E) REFUND OF FEE IF ORDER REQUEST
23 REFUSED FOR FILING OR WITHDRAWN BEFORE
24 FILING.—The Secretary shall refund 75 percent
25 of the fee paid under subparagraph (B) for any

1 order request which is refused for filing or was
2 withdrawn before being accepted or refused for
3 filing.

4 “(F) FEES FOR ORDER REQUESTS PRE-
5 VIOUSLY REFUSED FOR FILING OR WITHDRAWN
6 BEFORE FILING.—An OTC monograph order
7 request that was submitted but was refused for
8 filing, or was withdrawn before being accepted
9 or refused for filing, shall be subject to the full
10 fee under subparagraph (A) upon being resub-
11 mitted or filed over protest.

12 “(G) REFUND OF FEE IF ORDER REQUEST
13 WITHDRAWN.—If an order request is withdrawn
14 after the order request was filed, the Secretary
15 may refund the fee or a portion of the fee if no
16 substantial work was performed on the order
17 request after the application was filed. The Sec-
18 retary shall have the sole discretion to refund a
19 fee or a portion of the fee under this subpara-
20 graph. A determination by the Secretary con-
21 cerning a refund under this subparagraph shall
22 not be reviewable.

23 “(3) REFUNDS.—

24 “(A) IN GENERAL.—Other than refunds
25 provided pursuant to any of subparagraphs (D)

1 through (G) of paragraph (2), the Secretary
2 shall not refund any fee paid under paragraph
3 (1) except as provided in subparagraph (B).

4 “(B) DISPUTES CONCERNING FEES.—To
5 qualify for the return of a fee claimed to have
6 been paid in error under paragraph (1) or (2),
7 a person shall submit to the Secretary a written
8 request justifying such return within 180 cal-
9 endar days after such fee was paid.

10 “(4) NOTICE.—Within the timeframe specified
11 in subsection (c), the Secretary shall publish in the
12 Federal Register the amount of the fees under para-
13 graph (1) for such fiscal year.

14 “(b) FEE REVENUE AMOUNTS.—

15 “(1) FISCAL YEAR 2021.—For fiscal year 2021,
16 fees under subsection (a)(1) shall be established to
17 generate a total facility fee revenue amount equal to
18 the sum of—

19 “(A) the annual base revenue for fiscal
20 year 2021 (as determined under paragraph
21 (3));

22 “(B) the dollar amount equal to the oper-
23 ating reserve adjustment for the fiscal year, if
24 applicable (as determined under subsection
25 (c)(2)); and

1 “(C) additional direct cost adjustments (as
2 determined under subsection (c)(3)).

3 “(2) SUBSEQUENT FISCAL YEARS.—For each of
4 the fiscal years 2022 through 2025, fees under sub-
5 section (a)(1) shall be established to generate a total
6 facility fee revenue amount equal to the sum of—

7 “(A) the annual base revenue for the fiscal
8 year (as determined under paragraph (3));

9 “(B) the dollar amount equal to the infla-
10 tion adjustment for the fiscal year (as deter-
11 mined under subsection (c)(1));

12 “(C) the dollar amount equal to the oper-
13 ating reserve adjustment for the fiscal year, if
14 applicable (as determined under subsection
15 (c)(2));

16 “(D) additional direct cost adjustments (as
17 determined under subsection (c)(3)); and

18 “(E) additional dollar amounts for each
19 fiscal year as follows:

20 “(i) \$7,000,000 for fiscal year 2022.

21 “(ii) \$6,000,000 for fiscal year 2023.

22 “(iii) \$7,000,000 for fiscal year 2024.

23 “(iv) \$3,000,000 for fiscal year 2025.

24 “(3) ANNUAL BASE REVENUE.—For purposes
25 of paragraphs (1)(A) and (2)(A), the dollar amount

1 of the annual base revenue for a fiscal year shall
2 be—

3 “(A) for fiscal year 2021, \$8,000,000; and

4 “(B) for fiscal years 2022 through 2025,
5 the dollar amount of the total revenue amount
6 established under this subsection for the pre-
7 vious fiscal year, not including any adjustments
8 made under subsection (c)(2) or (c)(3).

9 “(c) ADJUSTMENTS; ANNUAL FEE SETTING.—

10 “(1) INFLATION ADJUSTMENT.—

11 “(A) IN GENERAL.—For purposes of sub-
12 section (b)(2)(B), the dollar amount of the in-
13 flation adjustment to the annual base revenue
14 for fiscal year 2022 and each subsequent fiscal
15 year shall be equal to the product of—

16 “(i) such annual base revenue for the
17 fiscal year under subsection (b)(2); and

18 “(ii) the inflation adjustment percent-
19 age under subparagraph (C).

20 “(B) OTC MONOGRAPH ORDER REQUEST
21 FEES.—For purposes of subsection (a)(2), the
22 dollar amount of the inflation adjustment to the
23 fee for OTC monograph order requests for fis-
24 cal year 2022 and each subsequent fiscal year
25 shall be equal to the product of—

1 years of the preceding 4 fiscal years,
2 multiplied by the proportion of per-
3 sonnel compensation and benefits
4 costs to total costs of OTC mono-
5 graph drug activities for the first 3
6 years of the preceding 4 fiscal years;
7 and

8 “(II) the average annual percent
9 change that occurred in the Consumer
10 Price Index for urban consumers
11 (Washington-Baltimore, DC–MD–VA–
12 WV; Not Seasonally Adjusted; All
13 items; Annual Index) for the first 3
14 years of the preceding 4 years of
15 available data multiplied by the pro-
16 portion of all costs other than per-
17 sonnel compensation and benefits
18 costs to total costs of OTC mono-
19 graph drug activities for the first 3
20 years of the preceding 4 fiscal years.

21 “(2) OPERATING RESERVE ADJUSTMENT.—

22 “(A) IN GENERAL.—For fiscal year 2021
23 and subsequent fiscal years, for purposes of
24 subsections (b)(1)(B) and (b)(2)(C), the Sec-
25 retary may, in addition to adjustments under

1 paragraph (1), further increase the fee revenue
2 and fees if such an adjustment is necessary to
3 provide operating reserves of carryover user
4 fees for OTC monograph drug activities for not
5 more than the number of weeks specified in
6 subparagraph (B).

7 “(B) NUMBER OF WEEKS.—The number of
8 weeks specified in this subparagraph is—

9 “(i) 3 weeks for fiscal year 2021;

10 “(ii) 7 weeks for fiscal year 2022;

11 “(iii) 10 weeks for fiscal year 2023;

12 “(iv) 10 weeks for fiscal year 2024;

13 and

14 “(v) 10 weeks for fiscal year 2025.

15 “(C) DECREASE.—If the Secretary has
16 carryover balances for such process in excess of
17 10 weeks of the operating reserves referred to
18 in subparagraph (A), the Secretary shall de-
19 crease the fee revenue and fees referred to in
20 such subparagraph to provide for not more than
21 10 weeks of such operating reserves.

22 “(D) RATIONALE FOR ADJUSTMENT.—If
23 an adjustment under this paragraph is made,
24 the rationale for the amount of the increase or
25 decrease (as applicable) in fee revenue and fees

1 shall be contained in the annual Federal Reg-
2 ister notice under paragraph (4) establishing
3 fee revenue and fees for the fiscal year involved.

4 “(3) ADDITIONAL DIRECT COST ADJUST-
5 MENT.—The Secretary shall, in addition to adjust-
6 ments under paragraphs (1) and (2), further in-
7 crease the fee revenue and fees for purposes of sub-
8 section (b)(2)(D) by an amount equal to—

9 “(A) \$14,000,000 for fiscal year 2021;

10 “(B) \$7,000,000 for fiscal year 2022;

11 “(C) \$4,000,000 for fiscal year 2023;

12 “(D) \$3,000,000 for fiscal year 2024; and

13 “(E) \$3,000,000 for fiscal year 2025.

14 “(4) ANNUAL FEE SETTING.—

15 “(A) FISCAL YEAR 2021.—The Secretary
16 shall, not later than the second Monday in May
17 of 2020—

18 “(i) establish OTC monograph drug
19 facility fees for fiscal year 2021 under sub-
20 section (a), based on the revenue amount
21 for such year under subsection (b) and the
22 adjustments provided under this sub-
23 section; and

1 “(ii) publish fee revenue, facility fees,
2 and OTC monograph order requests in the
3 Federal Register.

4 “(B) SUBSEQUENT FISCAL YEARS.—The
5 Secretary shall, for each fiscal year that begins
6 after September 30, 2021, not later than the
7 second Monday in March that precedes such fis-
8 cal year—

9 “(i) establish for such fiscal year,
10 based on the revenue amounts under sub-
11 section (b) and the adjustments provided
12 under this subsection—

13 “(I) OTC monograph drug facil-
14 ity fees under subsection (a)(1); and

15 “(II) OTC monograph order re-
16 quest fees under subsection (a)(2);
17 and

18 “(ii) publish such fee revenue
19 amounts, facility fees, and OTC mono-
20 graph order request fees in the Federal
21 Register.

22 “(d) IDENTIFICATION OF FACILITIES.—Each person
23 that owns an OTC monograph drug facility shall submit
24 to the Secretary the information required under this sub-

1 section each year. Such information shall, for each fiscal
2 year—

3 “(1) be submitted as part of the requirements
4 for drug establishment registration set forth in sec-
5 tion 510; and

6 “(2) include for each such facility, at a min-
7 imum, identification of the facility’s business oper-
8 ation as that of an OTC monograph drug facility.

9 “(e) EFFECT OF FAILURE TO PAY FEES.—

10 “(1) OTC MONOGRAPH DRUG FACILITY FEE.—

11 “(A) IN GENERAL.—Failure to pay the fee
12 under subsection (a)(1) within 20 calendar days
13 of the due date as specified in subparagraph
14 (D) of such subsection shall result in the fol-
15 lowing:

16 “(i) The Secretary shall place the fa-
17 cility on a publicly available arrears list.

18 “(ii) All OTC monograph drugs man-
19 ufactured in such a facility or containing
20 an ingredient manufactured in such a facil-
21 ity shall be deemed misbranded under sec-
22 tion 502(ff).

23 “(B) APPLICATION OF PENALTIES.—The
24 penalties under this paragraph shall apply until
25 the fee established by subsection (a)(1) is paid.

1 “(2) ORDER REQUESTS.—An OTC monograph
2 order request submitted by a person subject to fees
3 under subsection (a) shall be considered incomplete
4 and shall not be accepted for filing by the Secretary
5 until all fees owed by such person under this section
6 have been paid.

7 “(3) MEETINGS.—A person subject to fees
8 under this section shall be considered ineligible for
9 OTC monograph drug meetings until all such fees
10 owed by such person have been paid.

11 “(f) CREDITING AND AVAILABILITY OF FEES.—

12 “(1) IN GENERAL.—Fees authorized under sub-
13 section (a) shall be collected and available for obliga-
14 tion only to the extent and in the amount provided
15 in advance in appropriations Acts. Such fees are au-
16 thorized to remain available until expended. Such
17 sums as may be necessary may be transferred from
18 the Food and Drug Administration salaries and ex-
19 penses appropriation account without fiscal year lim-
20 itation to such appropriation account for salaries
21 and expenses with such fiscal year limitation. The
22 sums transferred shall be available solely for OTC
23 monograph drug activities.

24 “(2) COLLECTIONS AND APPROPRIATION
25 ACTS.—

1 “(A) IN GENERAL.—Subject to subpara-
2 graph (C), the fees authorized by this section
3 shall be collected and available in each fiscal
4 year in an amount not to exceed the amount
5 specified in appropriation Acts, or otherwise
6 made available for obligation, for such fiscal
7 year.

8 “(B) USE OF FEES AND LIMITATION.—
9 The fees authorized by this section shall be
10 available to defray increases in the costs of the
11 resources allocated for OTC monograph drug
12 activities (including increases in such costs for
13 an additional number of full-time equivalent po-
14 sitions in the Department of Health and
15 Human Services to be engaged in such activi-
16 ties), only if the Secretary allocates for such
17 purpose an amount for such fiscal year (exclud-
18 ing amounts from fees collected under this sec-
19 tion) no less than \$12,000,000, multiplied by
20 the adjustment factor applicable to the fiscal
21 year involved under subsection (c)(1).

22 “(C) COMPLIANCE.—The Secretary shall
23 be considered to have met the requirements of
24 subparagraph (B) in any fiscal year if the costs
25 funded by appropriations and allocated for OTC

1 monograph drug activities are not more than 15
2 percent below the level specified in such sub-
3 paragraph.

4 “(D) PROVISION FOR EARLY PAYMENTS IN
5 SUBSEQUENT YEARS.—Payment of fees author-
6 ized under this section for a fiscal year (after
7 fiscal year 2021), prior to the due date for such
8 fees, may be accepted by the Secretary in ac-
9 cordance with authority provided in advance in
10 a prior year appropriations Act.

11 “(3) AUTHORIZATION OF APPROPRIATIONS.—
12 For each of the fiscal years 2021 through 2025,
13 there is authorized to be appropriated for fees under
14 this section an amount equal to the total amount of
15 fees assessed for such fiscal year under this section.

16 “(g) COLLECTION OF UNPAID FEES.—In any case
17 where the Secretary does not receive payment of a fee as-
18 sessed under subsection (a) within 30 calendar days after
19 it is due, such fee shall be treated as a claim of the United
20 States Government subject to subchapter II of chapter 37
21 of title 31, United States Code.

22 “(h) CONSTRUCTION.—This section may not be con-
23 strued to require that the number of full-time equivalent
24 positions in the Department of Health and Human Serv-
25 ices, for officers, employers, and advisory committees not

1 engaged in OTC monograph drug activities, be reduced
2 to offset the number of officers, employees, and advisory
3 committees so engaged.

4 **“SEC. 744N. REAUTHORIZATION; REPORTING REQUIRE-**
5 **MENTS.**

6 “(a) PERFORMANCE REPORT.—Beginning with fiscal
7 year 2021, and not later than 120 calendar days after the
8 end of each fiscal year thereafter for which fees are col-
9 lected under this part, the Secretary shall prepare and
10 submit to the Committee on Energy and Commerce of the
11 House of Representatives and the Committee on Health,
12 Education, Labor, and Pensions of the Senate a report
13 concerning the progress of the Food and Drug Adminis-
14 tration in achieving the goals identified in the letters de-
15 scribed in section 3861(b) of the CARES Act during such
16 fiscal year and the future plans of the Food and Drug
17 Administration for meeting such goals.

18 “(b) FISCAL REPORT.—Not later than 120 calendar
19 days after the end of fiscal year 2021 and each subsequent
20 fiscal year for which fees are collected under this part,
21 the Secretary shall prepare and submit to the Committee
22 on Energy and Commerce of the House of Representatives
23 and the Committee on Health, Education, Labor, and
24 Pensions of the Senate a report on the implementation
25 of the authority for such fees during such fiscal year and

1 the use, by the Food and Drug Administration, of the fees
2 collected for such fiscal year.

3 “(c) PUBLIC AVAILABILITY.—The Secretary shall
4 make the reports required under subsections (a) and (b)
5 available to the public on the internet website of the Food
6 and Drug Administration.

7 “(d) REAUTHORIZATION.—

8 “(1) CONSULTATION.—In developing rec-
9 ommendations to present to the Congress with re-
10 spect to the goals described in subsection (a), and
11 plans for meeting the goals, for OTC monograph
12 drug activities for the first 5 fiscal years after fiscal
13 year 2025, and for the reauthorization of this part
14 for such fiscal years, the Secretary shall consult
15 with—

16 “(A) the Committee on Energy and Com-
17 merce of the House of Representatives;

18 “(B) the Committee on Health, Education,
19 Labor, and Pensions of the Senate;

20 “(C) scientific and academic experts;

21 “(D) health care professionals;

22 “(E) representatives of patient and con-
23 sumer advocacy groups; and

24 “(F) the regulated industry.

1 “(2) PUBLIC REVIEW OF RECOMMENDA-
2 TIONS.—After negotiations with the regulated indus-
3 try, the Secretary shall—

4 “(A) present the recommendations devel-
5 oped under paragraph (1) to the congressional
6 committees specified in such paragraph;

7 “(B) publish such recommendations in the
8 Federal Register;

9 “(C) provide for a period of 30 calendar
10 days for the public to provide written comments
11 on such recommendations;

12 “(D) hold a meeting at which the public
13 may present its views on such recommenda-
14 tions; and

15 “(E) after consideration of such public
16 views and comments, revise such recommenda-
17 tions as necessary.

18 “(3) TRANSMITTAL OF RECOMMENDATIONS.—
19 Not later than January 15, 2025, the Secretary
20 shall transmit to the Congress the revised rec-
21 ommendations under paragraph (2), a summary of
22 the views and comments received under such para-
23 graph, and any changes made to the recommenda-
24 tions in response to such views and comments.”.